



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,680	10/31/2001	Paul L Feldman	PU3318USw	6805

23347 7590 08/19/2003

DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/980,680

Applicant(s)
FELDMAN et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 9, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 20, 24-26, and 28-37 is/are pending in the application.
- 4a) Of the above, claim(s) 15-17, 19, 20, 26, 30, 31, 36, and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 10, 24, 25, 28, 29, and 32-35 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 8, 9, and 11-14 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 1-17, 19, 20, 24-26 and 28-37 are pending in the application.

Election/Restriction

1. Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 15-17, 19, 20, 26, 30, 31, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.
3. Claims 1, 24 and 32 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction. The Markush group represented by the variables R⁴, R⁵ and R⁶ have variably different definitions, rendering the claims clearly improper.

Specification

4. The amendment filed October 31, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

Art Unit: 1624

supported by the original disclosure is as follows: the moieties pyridylC₁₋₂alkyl and imidazolylC₁₋₂alkyl in the definition of R⁷.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. The disclosure is objected to because of the following informalities:
 - a) the amendment to the specification beginning on page 5, line 22 and continuing to page 6, line 9 includes a proviso within the definition for R⁴, where the R⁴ definition in the proviso is missing a vowel, i.e. "is"; and
 - b) the amendment to the specification beginning on page 6, line 25 and continuing to page 7, line 9 includes a proviso within the definition of R¹ where "then" is missing before the definition of X.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 10, 24, 25 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claim 1 and claims

Art Unit: 1624

dependent thereon where the definition of R⁷ is pyridylC₁₋₂alkyl and imidazolylC₁₋₂alkyl is not described in the specification. These moieties are not positively described in the specification with respect to formula (I).

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 6, 7, 24, 25, 28, 29, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 3 recites the limitation "0" in the definition of m. There is insufficient antecedent basis for this limitation in the claim. (See line 1 on page 7 of the amendment)
- b) Claim 3 is vague and indefinite in that it is not known what is meant by the proviso within the definition of R⁴ where the "then" is missing before the definition of X. (See line 6 on page 7 of the amendment)
- c) Claim 6 recites the limitation "2" in the definition of m. There is insufficient antecedent basis for this limitation in the claim. (See lines 19 and 23 on page 8 of the amendment)

Art Unit: 1624

- d) Claim 6 recites the limitation "2" in the definition of m. There is insufficient antecedent basis for this limitation in the claim. (See lines 7 and 18 on page 9 of the amendment)
- e) Claim 7 recites the limitation "2" in the definition of m. There is insufficient antecedent basis for this limitation in the claim. (See lines 2, 6 and 21 on page 10 of the amendment)
- f) Claims 24 and 25 provide for the method of use of the compounds of claims 1 and 10, respectively, which is unclear as to whether this is indicative of a subject in need thereof.
- g) Claims 28, 29 and claims dependent thereon are vague and indefinite in that the species are not stated as a Markush group. The compound according to claim 1, wherein the compound is or The compound according to formula (I), wherein the compound is is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1624

8. Claims 1-3, 24, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimamoto et al., Takeda Kenkyusho Ho. Shimamoto teaches the compounds, compositions and method of use of the compounds of formula (I) where R^1 is H; R^2 is phenyl; R^3 is chloro; R^4 is H; R^5 and R^6 together is O; W is H; X is CH_2 ; n is 1 or 2; Y is CH_2 ; m is 0 or 1; and p is 0. (Registry No. 29580-47-0)
9. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Walser et al., Journal of Organic Chemistry. Walser teaches the compounds of formula (I) where R^1 is CH_3 ; R^2 is phenyl; R^3 is chloro; R^4 is CH_3 ; R^5 and R^6 together is O; W is H; X is CH_2 ; n is 1 or 2; Y is CH_2 ; m is 0 or 1; and p is 0. (See example 4, Registry No. 40973-81-7)
10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbella et al., Journal of the Chemical Society, Chemical Communications. Corbella teaches the compounds of formula (I) where R^1 is CH_3 ; R^2 is phenyl; R^3 is chloro; R^4 is H; R^5 and R^6 together is O; W is H; X is CH_2 ; n is 1 or 2; Y is CH_2 ; m is 0 or 1; and p is 0. (Registry No. 51990-96-6)
11. Claims 1, 2, 24, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Manghisi et al., Bollettino Chimico Farmaceutico. Manghisi teaches the compounds, compositions and method of use of the compounds of formula (I) where R^1 is H; R^2 is phenyl; R^3 is chloro; R^4 is H; R^5 and R^6 together is O; W is H; X is CH_2 ; n is 1; m is 0; and p is 0. (Registry No. 55108-23-1 and 55108-27-5)

Art Unit: 1624

12. Claims 1-3, 24, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., EP 0 264 797. Wang teaches the compounds, compositions and method of use of the compounds of formula (I) where R¹ is H; R² is phenyl; R³ is chloro; R⁴ is CH₃; R⁵ and R⁶ together is O; W is H; X is CH₂; n is 1; m is 0; and p is 0. (See Fig. 11, Registry No. 119215-05-3)
13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bock et al., Journal of Heterocyclic Chemistry. Bock teaches the compounds of formula (I) where R¹ is CH₃ or 4-nitrophenyl; R² is phenyl; R³ is H; R⁴ is H; R⁵ and R⁶ together is O; W is H; X is CH₂ or NH; n is 2; m is 0; and p is 0. (Registry No. 129749-01-5 and 129749-05-9)
14. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bock et al., EP 0 508 798. Bock teaches the compounds of formula (I) where R¹ is CH₃; R² is phenyl; R³ is H; R⁴ is CH₃; R⁵ and R⁶ together is O; W is H; X is NH and CH₂; n is 2; Y is CH₂; m is 1; and p is 0. (See example 2a, Registry No. 145547-62-2)
15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bock et al., U.S. Patent No. 5,834,464. Bock teaches the compounds of formula (I) where R¹ is benzyl; R² is phenyl; R³ is H; R⁴ is H and R⁵ and R⁶ together is S; and R⁴ and R⁵ together form a double bond and R⁶ is NH(CH(CH₃)(CH₂OH)); W is H; X is NH; n is 1; m is 0; and p is 0. (See example 15, Registry No. 146135-15-1, 170228-05-4 and 170227-96-0)

Art Unit: 1624

16. Claims 1-3, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ichihara et al., JP 07-304755. Ichihara teaches the compounds and compositions of the compounds of formula (I) where R¹ is H or benzyl; R² is phenyl; R³ is H; R⁴ is H and CH₃; R⁵ and R⁶ together is O; W is H; X is CH₂; n is 1 or 2; Y is CH₂; m is 0 or 1; and p is 0. (Registry No. 174399-16-7, 174399-19-0, 174399-20-3, 174399-21-4, 174399-22-5, 174399-23-6, 174399-28-1, 174399-29-2 and 174399-30-5)

17. Claims 1-3, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lynch et al., WO 98/00405. Lynch teaches the compounds and compositions of the compounds of formula (I) where R¹ is ethyl or benzyl; R² is phenyl; R³ is H; R⁴ is H and CH₃; R⁵ and R⁶ together is S or O; W is H; X is NH; n is 1; Y is CH₂; m is 0 or 1; and p is 0. (See examples 65, 66, 98 and 107; Registry No. 146135-15-1, 170284-32-9, 170551-99-2, 108895-98-3 and 201988-64-9)

18. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertrand et al., EP 0 881 235. Bertrand teaches the compounds of formula (I) where R¹ is t-butyl; R² is phenyl; R³ is chloro; R⁴ is CH₃; R⁵ and R⁶ together is O; W is H; X is CH₂; n is 1; m is 0; and p is 0. (See example 3b₅)

19. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Goumri-Magnet et al., Journal of Organic Chemistry. Goumri-Magnet teaches the compounds of formula (I) where

Art Unit: 1624

R¹ is t-butyl; R² is phenyl; R³ is chloro; R⁴ is CH₃; R⁵ and R⁶ together is O; W is H; X is CH₂; n is 1; m is 0; and p is 0. (See example 7f)

Claim Objections

20. Claims 4, 5, 8, 9 and 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
August 15, 2003